K110979 OCT 20 2011

510(k) SUMMARY

1.0 Submitter:

Name: Mr Zahari Darus
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Date of Summary Prepared: March 2011 (revised 12 September 2011)

2.0 Name of the device:

DERMAGRIP ULTRA Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile (and various brandnames)

Common Name: Exam Gloves

Classification Name: Patient Examination Gloves (21 CFR 880.6250 product code LZA)

3.0 Identification of The Legally Marketed Devices:

Dermagrip Powder Free Blue Nitrile Examination Gloves
510(k) #: K022904
MDL: D36500
Regulatory Class I
Product code: LZA

4.0 Description of The Device:

Powder Free Nitrile Examination Gloves, Blue meet all the requirements of ASTM standard D6319-00a, D6124-06 and FDA 21 CFR 880.6250.

5.0 Intended Use of the Device:

The powder free examination glove is a specialty medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or forefinger to prevent contamination between examiner and patient bodily fluids, waste or environment.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves are summarized with the following technological characteristics compared to ASTM 6319-00a or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE (Both Predicate and Current)
Dimensions	ASTM D6319-10	Meets
Physical Properties	ASTM D6319-10	Meets
Thickness	ASTM D6319-10	Meets
Powder Free	ASTM D6124-06	Meets ≤ 2 mg/glove

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Biocompatability	Primary Skin Irritation – Consumer product safety Commission, Title 16, Chapter II, Part 1500:41 & 1500:3 (c)(4)	Passes (Not a primary skin irritant)
	Dermal Sensitization -Closed patch Test ISO 10993-10:2002(E)	Passes (Not a contact sensitizer)
Watertight (1000ml)	ASTM D5151-06	Passes

*Details and discussions of tests can be found in performance section

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above (ASTM Requirements).

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9.0 Conclusion

Powder Free Nitrile Examination Gloves, Blue will perform according to the gloves performance standards referenced in section 6.0 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, the device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Zahari Darus
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MALAYSIA

OCT 2 0 2011

Re: K110979
Trade/Device Name: DERMAGRIP ULTRA Powder Free Blue Nitrile Examination Gloves, Non-sterile (and various brandnames)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: September 19, 2011
Received: September 22, 2011

Dear Mr. Darus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K110979**

Applicant Name: **Advance Medical Products Sdn Bhd**

Device Name:

DERMAGRIP ULTRA Powder Free Blue Nitrile Examination Gloves, Non-sterile (and various brandnames)

Indications for Use:

The powder free examination glove is a specialty medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or forefinger to prevent contamination between examiner and patient bodily fluids, waste or environment.

Prescription Use ___No____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___YES____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110979